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| EXAMINER | |
|---|---|
| PURDY, KYLE A | |
| **ART UNIT** | **PAPER NUMBER** |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/598,112 | JUDY ET AL. | |
| | Examiner | Art Unit | |
| | Kyle Purdy | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08/17/2006 and 02/08/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *15-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) *7-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election Acknowledged/ Status of Application*

1. Applicants' election without traverse the invention of Group I encompassing claims 1-14 is acknowledged. The restriction is made final without traverse. Therefore, the restriction requirement is deemed to be proper and made final.

2. Claims 1-27 are pending and claims 1-14 are presented for examination on the merits. The following rejections are made.

### *Applicants Invention*

3. Applicants are claiming a tablet comprising a core comprising sumatriptan and a rapid release mantle free of sumatriptan wherein the mantle entirely surrounds the core.

### *Claim Objections*

4. Claims 7-9 are objected to because of the following informalities: claims are to end with a period. See MPEP 601.01(m). Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dandiker et al. (US 5425950; of record).**

Dandiker et al. ('Dandiker) is drawn to a controlled (sustained or immediate) release pharmaceutical composition. The composition of the reference comprises an (A) an outer layer free of sumatriptan and (B) an inner layer comprising an active $H_2$-serotonin antagonist or serotonin agonists such as sumatriptan (see abstract and column 14, lines 15-45; see instant claim 1). An exemplified formulation for an immediate release tablet is taught (see Example 10) wherein the tablet core possess a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose), a lubricant (sodium stearyl fumerate) and the drug sumatriptan. The tablet core is then coated with a polymer layer which comprises a filler (dibasic calcium phosphate), a binder (hydroxypropyl methylcellulose), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see instant claim 5). It is clear from Example 10 that, aside from sumariptan, the core and the coating contain substantially the same ingredients (see instant claim 10). It is also clear that upon coating of the core with the polymer layer, the core is entirely surrounded because the diameter and thickness both are substantially increased. The tablet formulation of Example 10 contains 50 mg of sumatriptan (see column 14, lines 30-35; see instant claim 4) and the weight ratio of mantle to core is 1.3:1 as the core had a weight of 100 mg and the coating had a weight of 130 mg (230 mg – 100 = 130 mg; see column 14, lines 45-50; see instant claims 2-3). This corresponds to a weight ratio of mantle to core of 1.3:1.

7. Thus, the limitations of the instant claims are met entirely by the reference of Dandiker.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 1-5 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US 5425950; of record) in view of Lerner et al. (US 2004/0052843).**

10. Dandiker et al. ('Dandiker) is drawn to a controlled (sustained or immediate) release pharmaceutical composition. specifically the invention comprises an (A) an outer layer free of sumatriptan and (B) an inner layer comprising an active $H_2$-serotonin antagonist or serotonin agonists such as sumatriptan (see abstract and column 14, lines 15-45; see instant claim 1). An exemplified formulation for a immediate release tablet is taught (see Example 10) wherein the tablet core possess a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose), a lubricant (sodium stearyl fumerate) and the drug sumatriptan. The tablet core is then coated with a polymer layer which comprises a filler (dibasic calcium phosphate), a binder (hydroxypropyl methylcellulose), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see instant claim 5). The core apart from the suamtriptan in the core contains substantially the same ingredients asa the mantle (see instant claim 10). Moreover, in the tablet formulation the core contains 50 mg of sumatriptan (see column 14, lines 30-35; see instant claim 4). The resulting core had a weight of 100 mg and the coating applied to a core had a weight of 130 mg (230 mg – 100 = 130 mg; see

column 14, lines 45-50). This corresponds to a weight ratio of mantle to core of 1.3:1 (see instant claims 2-3).

11. Dandiker fails to teach the tablet wherein both the core and the mantle dissolve rapidly in the stomach wherein at least 90% of the tablet is dissolved after 10 minutes. Dandiker also fails to teach that the core and the mantle disintegrate over substantially the same time period wherein the mantle is at least 95% dissolved and the core is at least 90% dissolved after 10 minutes.

12. Lerner et al. ('Lerner) is drawn to a controlled release dosage form having a zero order release profile. It is taught that drug delivery is to be tailored to the needs of therapy and that the delivery profile can be one of immediate release in the stomach (see [0003]; see instant claim 11). Example 5 of Lerner is drawn to a tablet possessing an inner core and an outer mantle. The inner core contains sumatriptan succinate, microcrystalline cellulose, lactose, croscarmellose sodium and magnesium stearate. The core is then coated with a mixture of sucrose, microcrystalline cellulose, menthol and magnesium stearate. The tablet was then tested for its drug release profile and it was found that 80% of the sumatriptan in the core was released in 30 minutes (see [0142]; see instant claims 13-14).

13. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teachings of Dandiker and Lerner with a reasonable expectation for success in arriving at a tablet comprising a core comprising sumatriptan and mantle free of sumatriptan wherein the weight ratio of the mantle to the core is less than 1.5:1. The significance of Dandiker is that it teaches the basic requirements for the excipients contained in the core and the mantle of the dosage form (see discussion above). However, Dandiker does not disclose any information regarding the rate of release such that sumatriptan is 90% released

within 10 minutes. However, Lerner describes properties similar to this limitation. Lerner teaches an immediate release dosage form that has a core and a mantle wherein the core contains sumatriptan and the mantle does not. It is taught that the formulation can be formulated for immediate release in the stomach. The reference teaches that the tablet (see discussion above) is capable of release 80% of the drug within 30 minutes in an aqueous system. However, one would have a reasonable expectation that subjecting to the dosage to the contents of the stomach would have similar properties if not an enhanced rate of dissolution. Moreover, the rate of disintegration of the core and mantle are similarly capable of optimization. It is well known in the art that if one desired to adjust the release profile for a capsule, adjusting the amount of disintegrant in the formulation would result in altering the rate of disintegration (i.e. adding more would increase the rate of dissolution while decreasing the amount would decrease the rate of dissolution), on the other hand if one desired to extend the drugs release from the dosage form, one would employ slow dissolving polymers or waxes. It is not inventive to determine and optimize the properties of a product taught by the prior art because optimization is routinely done in the field of formulations. And so if such an undertaking leads to the success of the invention, it is likely not a product of innovation but rather one of ordinary skill and common sense. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

14. **Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dandiker et al. (US 5425950) in view of Lieberman et al. (Pharma. Dosage Forms Vol. 1: tablets, 2nd edition, 1990, pp. 188-189).**

15. Dandiker et al. ('Dandiker) is drawn to a controlled (sustained or immediate) release pharmaceutical composition. specifically the invention comprises an (A) an outer layer free of sumatriptan and (B) an inner layer comprising an active $H_2$-serotonin antagonist or serotonin agonists such as sumatriptan (see abstract and column 14, lines 15-45; see instant claim 1). An exemplified formulation for a immediate release tablet is taught (see Example 10) wherein the tablet core possess a filler (microcrystalline cellulose), a binder (polyvinylpyrrolidone), a disintegrant (microcrystalline cellulose), a lubricant (sodium stearyl fumerate) and the drug sumatriptan. The tablet core is then coated with a polymer layer which comprises a filler (dibasic calcium phosphate), a binder (hydroxypropyl methylcellulose), a disintegrant (microcrystalline cellulose) and a lubricant (sodium stearyl fumerate) (see instant claim 5). Below are the amounts that each is contained in the tablet formulation of Example 10 (see instant claims 7-9):

**Core**

A) Drug: Sumatriptan, 50% w/w;

B) Filler: Microcrystalline cellulose, 23% w/w;

C) Binder: Polyvinylpyrrolidone, 2% w/w;

D) Disintegrant: Microcrystalline cellulose, 23% w/w;

E) Lubricant: sodium stearyl fumerate, 2% w/w;

F) Adsorbent: not specifically disclosed, no specified w/w %; and

G) Colorant: optional (see column 5, lines 65-68; see instant claim 6)

**Coating**

A') Filler: Dibasic calcium phosphate, 23% w/w

B') Binder: Hydroxypropyl methylcellulose, 35% w/w

C') Disintegrant: Microcrystalline cellulose, 40% w/w

D') Lubricant: Sodium stearyl fumerate, 1% w/w

E') Adsorbent: not specifically disclosed, no specified w/w %; and

F) Colorant: optional (see column 5, lines 65-68; see instant claim 6).

16. Dandiker fails to specifically teach the inclusion of an adsorbent.

17. Lieberman et al. ('Lieberman) is text book that teaches commonly used excipients in dosage formulations. Adsorbents are useful because they are capable of retaining large quantities of water without becoming wet and it is taught (and widely known) that adsorbents are commonly used in tablets in order to prevent sticking, picking and filming during the tableting process (see page 188; see instant claim 6). It is taught that adding an adsorbent is useful for adsorbing excess moisture which causes problems as those described.

18. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teaching of Dandiker with Lieberman with a reasonable expectation for success in arriving at a pharmaceutical dosage form comprising a core containing sumatriptan and a coating free of sumatriptan wherein the core and the mantle further comprises adsorbents and/or colorants. The significance of Dandiker is that it teaches the major features of the invention, a core containing sumatriptan and a coating of the core which is free of

sumatriptan. Dandiker also discloses that the core contains a filler, a binder, a disintegrant, and a lubricant while the mantle comprises a filler a binder a disintegrant and a lubricant either close to or within the specified weight limitations. The teaching of Dandiker fails to include an adsorbent in the tablet formulation. However, at the time the invention was made, one having an ordinarily level of skill in the art would be motivated to include an adsorbent in the formulation for the reasons evidenced by Lieberman. Lieberman states that adsorbents are commonly used to prevent sticking, picking and filming during tablet processing. In order to provide a consistent tablet including an adsorbent would be preferable. Further, if a tablet contained a drug sensitive to water (i.e. hydrolysis) the stability of the drug as well as the shelf-life of the composition could be seriously affected. Thus, one would be clearly motivated to include an adsorbent into the formulation for the two reasons disclosed above. Adding a colorant to a tablet would also useful because it allows one to recognize perhaps the type or quantity of medicament contained within the tablet. Therefore, the invention as a whole is *prima facie* obvious to one ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

## ***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/*
*Examiner, Art Unit 1611*
*March 17, 2008*

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615